



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2013-0171; FRL-9386-3]

Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA), this document announces that EPA is planning to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB). The ICR, titled: "Tier 2 Data Collection for Certain Chemicals Under the Endocrine Disruptor Screening Program (EDSP)" and identified by EPA ICR No. 2479.01 and OMB Control No. 2070-New, represents a new request related to the next phase of an existing program. Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection that is summarized in this document. The ICR and accompanying material are available in the docket for public review and comment.

DATES: Comments must be received on or before *[insert date 60 days after date of publication in the Federal Register]*.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2013-0171, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.htm>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Teresa Green, Office of Science Coordination and Policy (7203M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-8440; email address: green.teresa@epa.gov.

SUPPLEMENTARY INFORMATION:

I. What Information is EPA Particularly Interested in?

Pursuant to PRA section 3506(c)(2)(A) (44 U.S.C. 3506(c)(2)(A)), EPA specifically solicits comments and information to enable it to:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility.
2. Evaluate the accuracy of the Agency's estimates of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
3. Enhance the quality, utility, and clarity of the information to be collected.

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses. In particular, EPA is requesting comments from very small businesses (those that employ less than 25) on examples of specific additional efforts that EPA could make to reduce the paperwork burden for very small businesses affected by this collection.

5. EPA is specifically requesting comments on the duration of the time allotted for the Reproduction and Fertility Effects test (OCSPP Guideline 870.3800). The Agency is considering a range from 24 to 48 months, but for the purpose of the ICR calculations, it is assumed that all work will be completed within the 3-year duration of the ICR.

II. What Information Collection Activity or ICR Does this Action Apply to?

Title: Tier 2 Data Collection for Certain Chemicals Under the Endocrine Disruptor Screening Program (EDSP).

ICR number: EPA ICR No. 2479.01.

OMB control number: 2070-New.

ICR status: This ICR covers new information collection activities associated with the next phase of an existing program. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in Title 40 of the Code of Federal Regulations (CFR), after appearing in the **Federal Register** when approved, are listed in 40 CFR part 9, are displayed either by publication

in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers for certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: This ICR covers the information collection activities associated with Tier 2 data collection activities for certain chemicals under EPA's EDSP. The EDSP is established under section 408(p) of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 346a(p)), which requires EPA to develop a chemical screening program using appropriate validated test systems and other scientifically relevant information to determine whether certain substances may have hormonal effects. The EDSP consists of a two-tiered approach to screen chemicals for potential endocrine disrupting effects. The purpose of Tier 1 screening is to identify substances that have the potential to interact with the estrogen, androgen, or thyroid hormone systems using a battery of assays. Substances that have the potential to interact with estrogen, androgen or thyroid hormone systems may proceed to Tier 2, which is designed to identify any adverse endocrine-related effects caused by the substance, and establish a quantitative relationship between the dose and that endocrine effect. Additional information about the EDSP is available through the Agency's Web site at <http://www.epa.gov/endo>.

This ICR addresses the information collection activities for those chemicals that were screened under Tier 1 of the EDSP and are now proceeding to testing under Tier 2 of the EDSP. The ICR covers the full range of information collection activities associated with Tier 2 of the EDSP, including the paperwork activities associated with the issuance of Tier 2 orders, initial responses from order recipients, paperwork activities

associated with generating the data requested, and submitting the data to EPA pursuant to the order. Under the PRA, the ICR is intended to cover a 3-year period.

Burden statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to range between 204 and 9,750 hours, depending on the respondent category, with an estimated burden cost between \$18,842 and \$602,488. Burden is defined in 5 CFR 1320.3(b).

The ICR, which is available in the docket along with other related materials, provides a detailed explanation of the collection activities and the burden estimate that is only briefly summarized here:

Respondents/Affected Entities: Entities potentially affected by the collection activities in this ICR are those individuals and companies that receive an EDSP Tier 2 order issued by the Agency. Under FFDCA section 408(p)(5)(A), EPA "shall issue" EDSP test orders "to a registrant of a substance for which testing is required...or to a person who manufactures or imports a substance for which testing is required."

Estimated total number of potential respondents: 210.

Frequency of response: On occasion.

Estimated total average number of responses for each respondent: 1.

Estimated total annual burden hours: 110,750 hours.

Estimated total annual costs: \$7,375,603. This primarily represents estimated burden cost, with related administrative costs of \$104. Given the nature of the activities, there are no costs estimated for capital investment or maintenance and operational costs.

III. What is the Next Step in the Process for this ICR?

EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval pursuant to 5 CFR 1320.12. EPA will issue another **Federal Register** document pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB. If you have any questions about this ICR or the approval process, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

List of Subjects

Environmental protection, Chemicals, Endocrine disruptors, Pesticides and pests,
Reporting and recordkeeping.

Dated: May 14, 2013.

James Jones,

Acting Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2013-15035 Filed 06/21/2013 at 8:45 am; Publication Date: 06/24/2013]